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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,386	02/10/2004	Stephen F. Badylak	3220-74469	9910
23643 7590 01/10/2008 BARNES & THORNBURG LLP 11 SOUTH MERIDIAN INDIANAPOLIS, IN 46204			EXAMINER FORD, ALLISON M	
			ART UNIT 1651	PAPER NUMBER
			MAIL DATE 01/10/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/775,386

Applicant(s)

BADYLAK, STEPHEN F.

Examiner

Allison M. Ford

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 17-34 is/are pending in the application.
- 4a) Of the above claim(s) 17-23, 34 and 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

Applicants' response of 19 October 2007 has been received and entered into the application file. No claims have been added, amended or cancelled. Claims 17-34 remain pending in the current application, of which claims 17-23 and 28-34 have been withdrawn from consideration as being directed to non-elected inventions. Claims 24-27 have been considered on the merits.

### *Response to Arguments*

Applicant's arguments, see Response of 17 October 2007, with respect to the obviousness type double patenting rejections over US Patents 6,793,939 and 6,379,710 have been fully considered and are persuasive. The rejections of record have been withdrawn.

However, upon further consideration, the following new grounds of rejection are set forth:

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27 appears to define the method by which the tissue graft, implanted in the method of claim 24, is made; however, claim 27 recites the method of claim 24 *further* comprises preparing the gelled graft composition. It would appear to be more appropriate to recite: "The method of claim 24, wherein the gelled liver basement membrane tissue is prepared by providing a solution of fluidized liver basement membrane tissue, adding nutrients, and gelling the solution by adjusting the pH to about 6.0 to about 7.4." Correction is required.

*Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for forming endogenous tissue at a site in need thereof, by implanting a graft composition comprising an extracellular matrix consisting essentially of gelled liver basement membrane tissue of a warm-blooded vertebrate at the site in need of endogenous tissue growth, in an amount effective to induce endogenous tissue growth, wherein said liver basement membrane is devoid of endogenous cells associated with said liver tissue, does not reasonably provide enablement for formation of endogenous tissue at a site in need thereof by implanting a graft composition comprising gelled liver basement membrane tissue, without further limitation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The current claim language requires implantation of a composition defined only as *comprising* gelled liver basement membrane tissue of a warm-blooded vertebrate in an amount effective to induce endogenous tissue growth. The open transitional language "comprising" does not function to exclude any further elements or components, and thus reads on implantation of whole liver tissue which has been digested and gelled. However, according to the specification, it is necessary that the graft composition not include cells or cellular components endogenous to the liver tissue, but rather that the transplant material consist essentially of liver basement membrane substantially free of any cellular components (See Specification, Pg. 2, ln 15-20). Applicants stress that the liver basement membrane is non-immunogenic, thus its applicability in transplantation grafts; this is in contrast to whole (or full) liver

tissue, which would include immunogenic cells and cellular components which would raise problems with regards to immunotolerance in the recipient.

It is noted all examples in the specification are based on use of isolated liver basement membrane. Therefore, based on the teachings, guidance and working examples in the specification, it appears that Applicants have only enabled for a method for implanting a composition comprising an extracellular matrix consisting essentially of gelled liver basement membrane tissue of a warm-blooded vertebrate at the site in need of endogenous tissue growth in an amount effective to induce endogenous tissue growth, wherein said liver basement membrane is devoid of endogenous cells associated with said liver tissue. Please note that this language does not limit the graft composition to consist essentially of the liver basement membrane, but rather only limits the extracellular matrix, contained within the graft composition, to consist essentially of gelled liver basement membrane tissue, as is recited in the specification.

### *Conclusion*

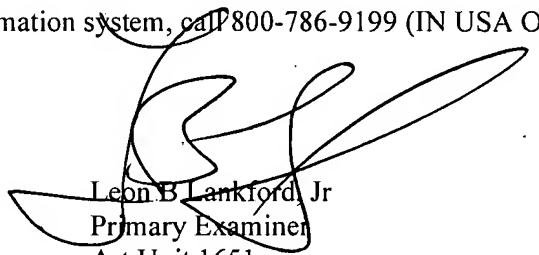
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M. Ford whose telephone number is 571-272-2936. The examiner can normally be reached on 7:30-5 M-Th, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leon B. Lankford, Jr.  
Primary Examiner  
Art Unit 1651